APR 1 3 2001

K002131

Summary of Safety and Effectiveness

Date Prepared: June 16, 2000

Submitter: Walter Lorenz Surgical, Inc.
1520 Tradeport Drive
Jacksonville, FL 32218-2480

Contact Person: Trevor Byrd

Product Code: 77LYA

Device Name: LactoSorb® Ethmoid Stent

Intended Use:
The LactoSorb® Ethmoid Stent is to be used during ethmoidectomy procedures.

The LactoSorb® Ethmoid Stent consists of a bioresorbable polymer which comes in a 25 x 25mm square with a thickness of .254mm. The stent is pre-folded into a "U" shape (12 x25mm) with 6 predrilled holes for ventilation in the sinus cavity.

The LactoSorb® resorbable copolymer is a synthetic polyester derived from lactic and glycolic acids. Polylactic/polyglycolic acid polymer degrades and resorbs IN VIVO by hydrolysis to lactic and glycolic acids, which are then metabolized by the body. The LactoSorb® material has been found to be biocompatible in both soft tissue and bone tissue.

Substantially Equivalence:

The LactoSorb® Ethmoid Stent is substantially equivalent to:

1. XoMed MeroGel™ Nasal Dressing and Sinus Stent K982731
2. XoMed T-Stent K973273
3. LactoSorb® Sheets K992158

The LactoSorb® Ethmoid Stent described in this notification has the same intended use characteristics as the XoMed MeroGel™ and T-Stent and is made from the same material used in the LactoSorb® Sheets.

Comparison to Marketed Devices

	XoMed MeroGel™ Nasal Dressing and Sinus Stent: K982731	XoMed T-Stent: K973273	LactoSorb® Sheets: K992158	LactoSorb® Ethmoid Stent
Indications	To be used in nasal/sinus surgery and /or trauma	Any sinus surgery requiring the placement of a drainage stent for the frontal sinus.	A. Trauma procedures of the midface or craniofacial skeleton. B. Reconstructive procedures of the midface or craniofacial skeleton C. Used to maintain the position of bone fragments in mandibular bone graft procedures and are used in conjunction with rigid internal fixation.	The LactoSorb® Ethmoid Stent is to be used during ethmoidectomy procedures.
Intended Use	The device is intended for use in the nasal/sinus cavities as a space-occupying dressing and/or stent, to separate mucosal surfaces and to help control minimal bleeding following surgery.	This device is intended for use as a postoperative stent to maintain an opening to the frontal sinus during the first 7 to 14 days following sinus surgical procedures. The self-retaining stent provides for the ventilation and drainage of fluids from the frontal sinus and helps prevent obstruction by adhesions when used alone or with other nasal stents or packs.	The LactoSorb® Sheets are intended for use in trauma or reconstructive procedures of the cranial-facial skeleton as well as to maintain the position of bony fractures in mandibular bone graft procedures.	The LactoSorb® Ethmoid Stent is intended to keep the middle turbinate away from the lateral nasal wall during the healing process after nasal/sinus surgery. The stent provides enough rigidity in the nasal cavity to keep the middle turbinate from adhering to the lateral nasal wall. The stent is held in place by the pressure of being wedged in between the turbinate and the wall.
Design	The original form of MeroGel™ is of a white fibrous material with a physical appearance similar to spun cotton. When it comes into contact with body fluids, it changes into a viscous and transparent gel.	The T-Stent is a one-piece radiopaque C-Flex thermoplastic elastomer drainage tube with T-shaped flanges at the proximal end for positioning and retention in the prepared sinus cavity.	a. Thickness: 0.25mm, 0.40mm, 0.50mm, 0.76mm, 1.1mm b. Sizes: 6.35x31.75mm Orbit shapes: left/right 200x200mm c. Predilled holes or drill as needed to accept LactoSorb® screws and rivets	25 x 25mm square with a thickness of .254mm. The stent is prefolded into a "U" shape (12x 25mm) with 6 predrilled holes for ventiliation in the sinus cavity.
Material	HYAFF®, an ester of hyaluronic acid	C-Flex Thermoplastic Elastomer	LactoSorb®- 82% PLLA/18% PGA	LactoSorb®- 82%PLLA/18%PGA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Trevor Byrd
Regulatory Specialist
Walter Lorenz Surgical, Inc.
1520 Tradeport Dr.
Jacksonville, FL 32218

Re: K002131
Trade Name: LactoSorb® Ethmoid Stent
Regulatory Class: I
CFR: 874.4780
Product Code: 77LYA
Dated: January 18, 2001
Received: January 19, 2001

Dear Mr. Byrd:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510 (k) NUMBER (IF KNOWN): K002131

DEVICE NAME: LactoSorb® Ethmoid Stent

INDICATIONS FOR USE:

The LactoSorb® Ethmoid Stent is indicated for use during ethmoidectomy procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use_____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002131